REMARKS

This amendment is in response to the Office Action of May 24, 2000, which has been received and reviewed. Claims 1-29 were pending in the application. Claims 3-7 and 9-11 have been canceled without prejudice or disclaimer. Reconsideration of the application is respectfully requested in light of the amendments and remarks presented herein.

**Priority**

The specification has been amended to include reference to the status of copending U.S. Application Ser. No. 09/177,814, filed October 23, 1998, as pending.

**Drawings**

Formal drawings will be provided upon receipt of a Notice of Allowance in the referenced application.

**Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-29 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In the rejection of claims 1, 6, and 7, the outstanding Office Action provides:

> "The term 'substantially' . . . is a relative term which renders the claim indefinite. The term 'substantially' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

With respect to claim 1, it is submitted that one of ordinary skill in the art would, in fact, understand that the phrase "substantially isolating" indicates that trace amounts of a constituent may remain in a sample despite separation of a significant amount of the constituent from the sample. *Andrew Corp. v. Gabriel Electronics,* 6 USPQ2d 2010 (Fed. Cir. 1988); M.P.E.P. § 2173.05(b)(D).

Claim 1 has been amended to provide antecedent basis for the phrase "porous capillary column" and to indicate that the constituent is being substantially separated from the sample.

For these reasons, it is respectfully requested that the Office withdraw the section 112, second paragraph, rejection of claim 1.

Claims 3, 4, 6, and 7 have been canceled without prejudice or disclaimer.

Claim 20 has been amended to recite "said analyzing", as suggested in the outstanding Office Action. In addition, it is respectfully submitted that use of the term "change" in the phrase "quantifying a change in said detection reagent" need not be specifically defined in claim 20 as this phrase may have several meanings, depending upon the type of separation being performed and the type of detection reagent employed, examples of which are clearly set forth in the specification. Further, it is respectfully submitted that the application of M.P.E.P. § 2173.05(d) in the section 112, second paragraph, rejection of claim 20 is improper, as M.P.E.P. § 2173.05(d) applies to use of phrases like "such as" and "for example" in claims, not to terms or phrases that have clear support in the specification. Therefore, it is respectfully requested that the section 112, second paragraph, rejections of claim 20 be withdrawn.

Claim 22 has been amended to recite "said stationary phase", for which antecedent basis is provided in claim 18. It is respectfully submitted that the recitation of "applying said stationary phase" is not inconsistent with the recitation of "a stationary phase disposed at a selected location along said capillary column" in claim 18 since claim 22 further limits the method recited in claim 18 to requiring that the stationary phase be applied to the matrix. Accordingly, it is respectfully requested that the section 112, second paragraph, rejections of claim 22 be withdrawn.

Claim 23 is allowable as depending from claims 22 and 18, as well as for the same reasons provided with respect to the recitation of "applying" in claim 22.

**Rejections Under 35 U.S.C. § 102**

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Isaka

Claims 1-5, 8, 9, 11, 14-16, 18-20, 22, 23, and 26-28 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,482,598 to Isaka et al. (hereinafter "Isaka").

Isaka discloses a chromatographic separation device that includes a silicon substrate and a single porous microchannel formed therein, as well as methods for fabricating and using such a chromatographic separation device.

As amended herein, claim 1 recites a separation method that includes applying a sample to an end of a capillary column that includes at least one capture substrate is disposed on a matrix of the porous capillary column and that the sample is drawn "across a flowfront through [the] porous capillary column so as to enhance separation of the constituent from the sample by [the] at least one capture substrate."

It is respectfully submitted that the enzyme disclosed in Isaka is not a capture substrate. As those of skill in the art are aware, an enzyme reacts with a substrate in a manner that detectably alters the substrate. By way of contrast, a capture substrate reacts with an analyte by capturing the analyte, and need not substantially alter the analyte. Accordingly, Isaka does not anticipate the subject matter recited in amended claim 1.

Claims 3-5, 9, and 11 have each been canceled without prejudice or disclaimer.

Claims 2, 8, and 14-16 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which should be allowed.

Claim 2 is further allowable since Isaka does not disclose "detecting [a] constituent with at least one detector disposed proximate a detecting region of [the] capillary column." Rather,

the enzymes disclosed in Isaka are not detectors, but are intended to alter one or more of the constituents of a sample to facilitate detection thereof.

Independent claim 18 recites a method that includes, among other things, detecting the binding of a constituent and a stationary phase. Isaka does not disclose detection of the binding of a constituent with a stationary phase. Rather, Isaka discloses that an unbound constituent can itself be detected upon exiting a porous capillary column. Accordingly, it is respectfully submitted that Isaka does not anticipate each and every element of independent claim 18.

Claims 19, 20, 22, 23, and 26-28 are each allowable, among other reasons, as depending either directly or indirectly from claim 18, which should be allowed.

Claim 19 is further allowable since Isaka does not disclose "analyzing [a] detection reagent to determine whether [a] constituent is present." Rather, Isaka discloses the use of a fluorescent die to detect bands obtained during electrophoretic separation, which, as those of skill in the art are aware, typically involves the use of a nonspecific fluorescent dye to illuminate all of the electrophoretically separated bands. Moreover, the enzymes disclosed in Isaka are not used as detection reagents, but rather to modify a sample constituent to a detectable form.

Claim 20, which depends from claim 19, is also allowable since Isaka does not disclose "quantifying a change in [a] detection reagent."

For the foregoing reasons, it is respectfully submitted that claims 1, 2, 8, 14-16, 18-20, 22, 23, and 26-28 are allowable under 35 U.S.C. § 102(b). It is, therefore, respectfully requested that the 35 U.S.C. § 102(b) rejections of each of these claims be withdrawn.

Northrup

Claims 10, 17, and 29 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,882,496 to Northrup et al. (hereinafter "Northrup").

Northrup discloses, among several other things, a electrophoretic separation device that includes porous columns formed internally within a silicon substrate. Electrodes are positioned at opposite ends of the substrate so as to facilitate the movement of the constituents of a sample along the lengths of the columns. Northrup also discloses methods for fabricating such an electrophoretic separation device.

Claim 10 has been canceled without prejudice or disclaimer.

Claims 17 and 29 are each allowable, among other reasons, as depending from claims 1 and 18, respectively, both of which should be allowed.

**Rejections Under 35 U.S.C. § 103(a)**

It is respectfully submitted that to establish a *prima facie* case of obviousness under 35 U.S.C. § 103 three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the cited prior art reference must teach or suggest all of the claim limitations. Furthermore, the suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure.

Isaka in View of Sunzeri and Swedberg

Claims 12, 13, 21, 24, and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,536,382 to Sunzeri et al. (hereinafter "Sunzeri") and U.S. Patent 5,571,410 to Swedberg et al. (hereinafter "Swedberg").

The teachings of Isaka were summarized previously herein.

Sunzeri teaches a method for analyzing the constituents of human biological fluids. A labeled specific binding pair member is added to a human biological fluid to effect binding between an analyte in the human biological fluid and the specific binding pair member. The constituents of the human biological fluid, including complexes of the analyte and the specific binding pair member, are separated by way of known capillary electrophoresis techniques. The separation obtained by way of capillary electrophoresis is then compared to a control, which provides a standard for quantitation by indicating the position where the analyte would have been present if it had not been bound by the labeled specific binding pair member. The specific

binding pair member is not immobilized to the matrix of the capillary electrophoresis substrate, but rather is permitted to travel therethrough with the bound analyte.

Swedberg teaches a miniaturized separation apparatus including a column within which a porous quantity of biocompatible material, such as "nylon, cellulose, polymethylmethacrylate, polyacrylamide, agarose, or the like" may be disposed. Col. 27, lines 37-40. Each of these materials have long been used in separating the constituents of biological samples. Swedberg does not teach that the porous matrix is formed in the substrate. Rather, a quantity of biocompatible, porous material is placed into an open column.

Claims 12 and 13 are each allowable, among other reasons, as depending from claim 1, which should be allowed.

Claims 21, 24, and 25 are each allowable, among other reasons, as depending from claim 18, which should be allowed.

Moreover, it is respectfully submitted that one of skill in the art would not be motivated to combine the teachings of Isaka with those of Sunzeri and Swedberg in the manner that has been set forth in the outstanding Office Action. While Sunzeri teaches binding of an analyte and a labeled specific binding pair member, the specific binding pair member of Sunzeri is not immobilized to a capillary electrophoresis substrate, as is the capture molecule taught in Swedberg. Isaka includes no teaching or suggestion that a specific binding pair member or capture molecule would be useful in separation techniques that utilize the apparatus disclosed therein. Further, as Swedberg teaches a method for forming a miniaturized separation apparatus that includes forming an open trench in a substrate and filling the trench with a different, synthetic porous material, it is respectfully submitted that one of skill in the art would not have been motivated to apply the teachings of Swedberg to the subject matter taught in Isaka. Moreover, as different types of matrix materials are used in the columns of the devices taught in Isaka and Swedberg, one in the art would not have been motivated to use the same chemistries to bind capture substrates to porous silicon as those employed to bind capture substrates to the material used in the columns of the Swedberg device.

Swedberg also provides that the particular column substrates disclosed therein were "selected to avoid the inherent chemical activity and pH instability encountered with silicon and

prior silicon dioxide-based device substrates", such as the porous silicon substrate taught by Isaka. Thus, when read by one of ordinary skill in the art, Swedberg would actually teach away from the attempted combination thereof with Isaka.

Isaka in View of Yu

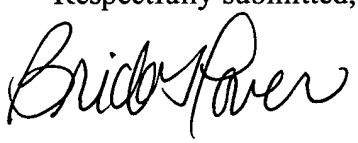
Claims 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,583,281 to Yu (hereinafter "Yu").

Claims 6 and 7 have been canceled without prejudice or disclaimer.

CONCLUSION

It is respectfully submitted that claims 1, 2, 8, and 12-29 are allowable. An indication of the allowability of each of these claims and a notice that the case has been passed for issue are respectfully solicited at an early date. If any issues remain that prevent the allowance of any of claims 1, 2, 8, and 12-29 and that might be resolved by way of a telephone conference, the Office is respectfully invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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